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PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:

Attorney Docket No.: 3099.12US02

Hevey

Confirmation No.: 5829

Application No.: 10/025,037

Examiner: Evans, Charesse L.

Filed: December 19, 2001

Group Art Unit: 1615

For: MEDIUM AND METHOD FOR DELIVERY OF EDIBLE MATERIALS SUBJECT TO
DEGRADATION BY OXIDATION AND HYDROLYSIS

TRANSMITTAL OF APPEAL BRIEF

Mail Stop - Appeal Brief - Patents
Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

X Transmitted herewith is an Appeal Brief (in triplicate).

X Small entity status of this application under 37 CFR 1.27 has been established by
verified statement previously submitted.

 A verified statement to establish small entity status under 37 CFR 1.9 and 1.27 is
enclosed.

X A check in the amount of \$165.00 to cover the fee for filing the appeal for a small entity
as set forth in 37 CFR 1.17(f).

Respectfully submitted,

Kimberly K. Baxter
Registration No. 40,504



Application No. 10/025,037


Patterson, Thuente, Skaar & Christensen, P.A.
4800 IDS Center
80 South 8th Street
Minneapolis, Minnesota 55402-2100
Telephone: (612) 349-5750

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Kimberly K. Baxter



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For: MEDIUM AND METHOD FOR DELIVERY OF EDIBLE MATERIALS SUBJECT TO
DEGRADATION BY OXIDATION AND HYDROLYSIS

APPELLANT'S BRIEF (37 CFR § 1.192)

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Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This brief is in furtherance of the Notice of Appeal filed in this case on October 23, 2003. This brief is transmitted in triplicate pursuant to 37 CFR § 1.192(a). The fees required under § 1.17(f) for filing this brief are dealt with in the accompanying TRANSMITTAL OF APPEAL BRIEF.

I. REAL PARTY IN INTEREST (37 C.F.R. § 1.192(c)(1))

The real party in interest to the appeal on the above-referenced application is Global Access, Inc., the assignee of the subject matter disclosed and claimed therein.

II. RELATED APPEALS AND INTERFERENCES (37 C.F.R. § 1.192(c)(2))

Appellant and its legal representatives know of no other appeals or interferences that will directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.

III. STATUS OF CLAIMS (37 C.F.R. § 1.192(c)(3))

This is a utility application. The claims of the application stand rejected under 35 U.S.C. § 103(a) pursuant to a final rejection mailed on July 28, 2003, and an Advisory Action mailed October 15, 2003. Claims 1-25 of the application are on appeal.

IV. STATUS OF AMENDMENTS (37 C.F.R. § 1.192(c)(4))

No amendments were made after the final rejection. The response after final was considered by the Examiner and responded to in an Advisory Action affirming the previous rejection.

V. SUMMARY OF INVENTION (37 C.F.R. § 1.192(c)(5))

The invention relates to a palatable, viscous carrier for delivering a variety of ingestible substances such as dietary supplements, therapeutic agents, vitamins and other probiotic agents. The viscous carrier protects the ingestible substances from exposure to a variety of environments capable of degrading the quality of the substances. For example, such protection can relate to protection from exposure to atmospheric oxygen or stomach acids. The viscous carrier is also capable of delivery through a variety of common and inexpensive delivery vehicles.

With respect to claims 1-6, the present invention relates to a viscous carrier comprising a combination of vegetable oil, fish oil and antioxidants as described at Page 5, Lines 14-16. The

vegetable oils can be selected from a number of alternatives as described at Page 5, Lines 18 – Page 6, Line 3. The fish oil can also be selected from a number of alternatives as described at Page 6, Lines 4-5. The antioxidants can be selected from a number of alternatives as described at Page 6, Lines 7-10.

With respect to the claims 7-18, the present invention further relates to a ingestible food supplement in a viscous carrier as described at Page 5, Lines 14-17. The viscous carrier comprises a combination of vegetable oil, fish oil and antioxidants as described at Page 5, Lines 14-16. The vegetable oils can be selected from a number of alternatives as described at Page 5, Lines 18 – Page 6, Line 3. The fish oil can also be selected from a number of alternatives as described at Page 6, Lines 4-5. The antioxidants can be selected from a number of alternatives as described at Page 6, Lines 7-10. The supplement also comprises active ingredients as described at Page 7, Lines 18-22.

With respect to claims 19-25, the present invention relates to a method for delivering probiotic substances utilized in dietary supplements to an intestinal tract as described at Page 8, Lines 1-12. Specific formulas are further described from Page 9, Line 1 – Page 17, Line 7.

VI. ISSUES (37 C.F.R. § 1.192(c)(6))

The issue relevant to this appeal is whether the Applicant's invention is properly rejected under 35 U.S.C. § 103(a) as being unpatentable over Gehrman et al. (U.S. Patent No. 4,518,696) in view of Desai et al. (U.S. Patent No. 4,867,986). Applicant respectfully asserts said rejection is improper as there is no motivation to combine the references.

VII. GROUPING OF CLAIMS (37 C.F.R. § 1.192(c)(7))

Claims 1-25 are presently pending in this appeal. For purposes of this appeal, the pending claims are grouped in three groups. A first group comprising claims 1-13, 17 and 18. A second group comprising claims 14-16. A third group comprises claims 19-25.

VIII. ARGUMENT REGARDING THE EXAMINER'S REJECTION UNDER 35 U.S.C. § 103(a) (37 C.F.R. § 1.192(c)(8)(v))

A. The Examiner has failed to establish a *prima facie* case of obviousness under 35 U.S.C. § 103(a).

1. Claims 1-13, 17 and 18

A criteria to establish a *prima facie* case of obviousness is that there must be some suggestion or motivation either in the references themselves or in the knowledge generally available to one of ordinary skill in the art to combine the reference teachings. MPEP 2142-2143. In re Vaeck, 947 F.2d 488, 20 USPQ 2d 1438 (Fed. Cir. 1991). Applicant submits that there is no motivation to combine the Desai reference with the Gehrman reference.

First, the Gehrman reference and Desai reference disclose two distinct forms of delivery. Gehrman discloses a liquid suspension of dry viable *Lactobacillus* cells in sunflower seed oil. Desai et al. teaches a microemulsion of marine animal oils, present as microspheres or macrospheres, encased within gelatin. Due to the distinct forms of the references, i.e., a liquid versus a gel, it is not reasonable to infer that the combination of the references would in fact lead to the formulation of a stabilized and shelf-stable mixture for use in various product mixtures.

Secondly and most importantly, the Gehrman and Desai references teach away from the Examiner's suggested combination. In general, a reference may be said to teach away from its combination with a second reference if a person of ordinary skill in the art, upon reading the first reference, would be led in a direction divergent from the path that was taken by the Applicant. In re Gurley, 27 F.3d 551, 31 USPQ 2d 1130 (Fed. Cir. 1994). As stated previously, the Gehrman reference teaches away from utilizing the elements of Desai because the Gehrman reference states that sunflower seed oil is preferably the "**only**" liquid ingredient of the medium. See Column 2, lines 61-63 of Gehrman. Even more explicitly, the Gehrman reference states that testing the preservation properties of other oils leads to the conclusion that, "...sunflower oil has special properties for maximizing the preservation of Lactobacilli in oil suspension." See Column 5, lines 21-23. Not only would combining the fish oil and antioxidants of Desai with Gehrman nullify the desired invention of Gehrman, i.e., a suspension medium having sunflower oil as its only liquid, it would also be contrary to the teaching of Gehrman which explicitly categorizes sunflower oil, as having special, advantageous preservation properties.

In light of the Gehrman reference, it cannot reasonably be said that a person skilled in the art would infer that the addition of fish oil or antioxidants would result in the formulation of a stabilized and shelf-stable mixture in light of the special preservation properties of sunflower oil as described by Gehrman. Instead, a person of reasonable skill in the art would avoid adding the fish oil and antioxidants of Desai for fear of detrimentally effecting the special preservation properties of sunflower oil as described by Gehrman. Furthermore, it cannot reasonably be asserted that a person skilled in the art would be motivated to combine the fish oil and

antioxidants of Desai such that the sunflower oil of Gerhman, including its special preservation properties, is present at a weight percent of only 45-55%, as claimed by the present invention.

The present claims are directed to a composition with 45% to 55% vegetable oil. On the other hand, the Desai reference teaches a composition wherein the gelatin comprises anywhere from 30% to 75% by weight of the product (See Column 6, Lines 12-45) while the marine animal oil comprises at least 5%, but most preferably 25% to 75% of the product by weight (See Column 5, Line 65 – Column 6, Line 45). The preferred ranges described and the specific embodiments contemplated by the Desai reference simply do not allow for the inclusion of 45% to 55% vegetable oil. Thus, the Desai reference teaches away from Applicant's claimed invention as well as teaching away from its combination with the Gehrman reference to modify the teachings of the Gehrman reference to obtain Applicant's claimed invention.

Due to the fact that there is no suggestion or motivation to combine the cited references and that instead, the references teach away from such a combination, the modification suggested by the Examiner can only be based on hindsight using Applicant's specification as a template to guide the modification. Such hindsight reasoning based on Applicant's own specification is not appropriate. See MPEP 2141.01(III).

The Examiner rejected Applicant's arguments based on an assertion that the motivation to combine flowed from the fact that both references were directed to compositions comprising oil. But this analysis reduces a Graham analysis, as mandated by the Supreme Court, to a triviality and neglects the statutory mandate for an obviousness analysis to be based on "the whole" with respect to the claim and the cited art. See, for example, MPEP 2141.02 AND 35 U.S.C. § 103(a). As summarized by the MPEP 2141.02 in a bold heading - "**PRIOR ART**

MUST BE CONSIDERED IN ITS ENTIRITY, INCLUDING DISCLOSURES THAT TEACH AWAY FROM THE CLAIMS." Furthermore, the fact that references can be combined does not render the combination obvious unless the prior art suggests the desirability of the combination. MPEP2143.01, citing *In re Mills*, 16 U.S.P.Q.2d 1430, (Fed. Cir. 1990).

Applicant respectfully submits that the Examiner has failed to establish a case for *prima facie* obviousness and requests that the rejection of claims 1-13, 17 and 18 under 35 USC § 103(a) be withdrawn.

B. Claims 14-16

The Examiner has the burden to establish *prima facie* unpatentability. Furthermore, obviousness must be based on the teaching in the art of all of the claim features. See, for example, MPEP 2143.03, entitled, "All Claim Limitations Must Be Taught or Suggested." Yet, the Examiner has stated nothing regarding the features of claims 14-16. Therefore, *prima facie* obviousness has clearly not been established for these claims.

Applicant respectfully requests withdrawal of the rejection of claims 14-16.

C. Claims 19-25

A criteria to establish a *prima facie* case of obviousness is that there must be some suggestion or motivation either in the references themselves or in the knowledge generally available to one of ordinary skill in the art to combine the reference teachings. MPEP 2142-2143. *In re Vaeck*, 947 F.2d 488, 20 USPQ 2d 1438 (Fed. Cir. 1991). As discussed previously with respect to claims 1-13, 17 and 18, Applicant, based on the same reasoning as previously



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supplied with respect to claims 1-13, 17 and 18, again submits that there is no motivation to combine the Desai reference with the Gehrman reference.

Secondly, even if the Desai reference and the Gehrman reference are combined, the combination fails to disclose a step of heating and mixing a combination of vegetable oils and fish oils to create a clear and homogeneous mixture. "To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art." MPEP 2143.03, citing *In re Royka*, 180 U.S.P.Q. 580, (CCPA 1974). As this step is neither taught nor suggested by the Desai and Gehrman references, the Examiner has failed to establish *prima facie* obviousness.

Respectfully submitted,

Kimberly K. Baxter
Registration No. 40,504

Patterson, Thuente, Skaar & Christensen, P.A.
4800 IDS Center
80 South 8th Street
Minneapolis, Minnesota 55402-2100
Telephone: (612) 349-5750

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December 23, 2003
Date of Deposit

Kimberly K. Baxter

IX. APPENDIX (37 C.F.R. § 1.192(c)(9))

The claims involved in this appeal are provided below.

1. (Original) A palatable viscous carrier for ingestible substances subject to degradation by environmental factors such as oxidation, hydrolysis, or low pH comprising in weight percent based upon the weight of the palatable viscous carrier:

from 45% to 55% vegetable oil;

from 1% to 5% fish oil; and

from 0.25% to 1.0% exogenous antioxidants.

2. (Original) The carrier as claimed in claim 1, in which the vegetable oil comprises one or more substances selected from a group consisting of canola oil, helianthus annus oil, hydrogenated vegetable oil, borage seed oil, evening primrose oil, avocado oil, sweet almond oil, canola oil, grape seed oil, jojoba oil, apricot kernal oil, safflower oil, sesame oil, hybrid safflower oil, soybean oil, sunflower seed oil, and macadamia nut oil.

3. (Original) The carrier as claimed in claim 1, in which the fish oil comprises one or more substances selected from a group consisting of cod liver oil, tuna oil, salmon oil, and sardine oil.

4. (Original) The carrier as claimed in claim 1, in which the exogenous antioxidant comprises tocopherol.

5. (Original) The carrier as claimed in claim 4, in which the tocopherol comprises one or more substances selected from a group consisting of alpha tocopherol, beta tocopherol, gamma tocopherols and delta tocopherols.

6. (Original) The carrier as claimed in claim 1, further comprising one or more substances selected from a group consisting of flavoring, plant extracts, starches, hydrophobic polyols, and coloring agents.

7. (Original) A palatable probiotic ingestible food supplement in a viscous carrier, the food supplement comprising in weight percent based upon the weight of the palatable probiotic ingestible food supplement:

from 45% to 55% vegetable oil;

from 1% to 5% fish oil; and

from 0.25% to 1.0% exogenous antioxidants; and

from 0.1% to 5% probiotic ingredients.

8. (Original) The food supplement as claimed in claim 7, in which the vegetable oil comprises one or more substances selected from a group consisting of canola oil, helianthus annus oil, hydrogenated vegetable oil, borage seed oil, evening primrose oil, avocado oil, sweet almond oil, canola oil, grape seed oil, jojoba oil, apricot kernal oil, safflower oil, sesame oil, hybrid safflower oil, soybean oil, sunflower seed oil, and macadamia nut oil.

9. (Original) The food supplement as claimed in claim 7, in which the fish oil comprises one or more substances selected from a group consisting of cod liver oil, tuna oil, salmon oil, and sardine oil.
10. (Original) The food supplement as claimed in claim 7, in which the exogenous antioxidant comprises tocopherol.
11. (Original) The food supplement as claimed in claim 10, in which the tocopherol comprises one or more substances selected from a group consisting of alpha tocopherol, beta tocopherol, gamma tocopherols, and delta tocopherols.
12. (Original) The food supplement as claimed in claim 7, further comprising one or more substances selected from a group consisting of flavoring, plant extracts, starches, hydrophobic polyols, and coloring agents.
13. (Original) The food supplement as claimed in claim 7, in which the probiotic ingredients comprise one or more substances selected from a group consisting of freeze-dried probiotic microorganisms, antibiotics, oil soluble, and water soluble vitamins, enzymes, salts of bioactive ingredients and polysaccharides.
14. (Original) The food supplement as claimed in claim 7, further comprising papain.

15. (Original) The food supplement as claimed in claim 17, in which the probiotic ingredients is one or more substances selected from a group consisting glucosamine hydrochloride, glucosamine sulfate, and chondroitin sulfate.

16. (Original) The food supplement as claimed in claim 7, further comprising fructooligosaccharides.

17. (Original) The food supplement as claimed in claim 7, in which the probiotic ingredients comprise microorganisms.

18. (Original) The food supplement as claimed in claim 17, in which the microorganisms comprise one or more selected from a group consisting of lactobacillus acidophilus, lactobacillus rhamnosus, enterococcus faecium, lactobacillus helveticus, and lactobacillus plantarum
lactobacillus acidophilus, lactobacillus rhamnosus, and lactobacillus plantarum.

19. (Original) A method for delivering probiotic substances utilized in dietary supplements to an intestinal tract, the method comprising the steps of:

heating and mixing natural occurring ingestible oils comprising vegetable oils and
fish oils until a resulting mixture is clear and homogeneous;
cooling said resulting mixture to a viscous state and to a temperature that will not
harm the probiotic substances;

adding the probiotic substances to the cooled mixture and mixing such that the probiotic substances are coated with the cooled mixture whereby an ingestible, viscous dietary supplement is produced.

20. (Original) The method as claimed in claim 19, in which the vegetable oils are selected from a group consisting of canola oil, helianthus annus oil, hydrogenated vegetable oil, borage seed oil, evening primrose oil, avocado oil, sweet almond oil, canola oil, grape seed oil, jojoba oil, apricot kernal oil, safflower oil, sesame oil, hybrid safflower oil, soybean oil, sunflower seed oil, and macadamia nut oil.

21. (Original) The method as claimed in claim 19, in which the fish oils comprise one or more substances selected from a group consisting of cod liver oil, tuna oil, salmon oil, and sardine oil.

22. (Original) The method as claimed in claim 19, further comprising the step of adding one or more substances selected from a group consisting of flavoring, plant extracts, starches, hydrophobic polyols, and coloring agents.

23. (Original) The method as claimed in claim 19, in which the probiotic substances comprise one or more substances selected from a group consisting of freeze-dried probiotic microorganisms, antibiotics, oil soluble, and water soluble vitamins, enzymes, salts of bioactive ingredients, and polysaccharides.

24. (Original) The method as claimed in claim 19, in which the probiotic substances comprise one or more substances selected from a group consisting glucosamine hydrochloride, glucosamine sulfate, and chondroitin sulfate.

25. (Original) The method as claimed in claim 19, in which the probiotic substances comprise one or more microorganisms selected from a group consisting of lactobacillus acidophilus, lactobacillus rhamnosus, enterococcus faecium, lactobacillus helveticus, and lactobacillus plantarum lactobacillus acidophilus, lactobacillus rhamnosus, and lactobacillus plantarum.



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Sir:

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II. RELATED APPEALS AND INTERFERENCES (37 C.F.R. § 1.192(c)(2))

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III. STATUS OF CLAIMS (37 C.F.R. § 1.192(c)(3))

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V. SUMMARY OF INVENTION (37 C.F.R. § 1.192(c)(5))

The invention relates to a palatable, viscous carrier for delivering a variety of ingestible substances such as dietary supplements, therapeutic agents, vitamins and other probiotic agents. The viscous carrier protects the ingestible substances from exposure to a variety of environments capable of degrading the quality of the substances. For example, such protection can relate to protection from exposure to atmospheric oxygen or stomach acids. The viscous carrier is also capable of delivery through a variety of common and inexpensive delivery vehicles.

With respect to claims 1-6, the present invention relates to a viscous carrier comprising a combination of vegetable oil, fish oil and antioxidants as described at Page 5, Lines 14-16. The

vegetable oils can be selected from a number of alternatives as described at Page 5, Lines 18 – Page 6, Line 3. The fish oil can also be selected from a number of alternatives as described at Page 6, Lines 4-5. The antioxidants can be selected from a number of alternatives as described at Page 6, Lines 7-10.

With respect to the claims 7-18, the present invention further relates to a ingestible food supplement in a viscous carrier as described at Page 5, Lines 14-17. The viscous carrier comprises a combination of vegetable oil, fish oil and antioxidants as described at Page 5, Lines 14-16. The vegetable oils can be selected from a number of alternatives as described at Page 5, Lines 18 – Page 6, Line 3. The fish oil can also be selected from a number of alternatives as described at Page 6, Lines 4-5. The antioxidants can be selected from a number of alternatives as described at Page 6, Lines 7-10. The supplement also comprises active ingredients as described at Page 7, Lines 18-22.

With respect to claims 19-25, the present invention relates to a method for delivering probiotic substances utilized in dietary supplements to an intestinal tract as described at Page 8, Lines 1-12. Specific formulas are further described from Page 9, Line 1 – Page 17, Line 7.

VI. ISSUES (37 C.F.R. § 1.192(c)(6))

The issue relevant to this appeal is whether the Applicant's invention is properly rejected under 35 U.S.C. § 103(a) as being unpatentable over Gehrman et al. (U.S. Patent No. 4,518,696) in view of Desai et al. (U.S. Patent No. 4,867,986). Applicant respectfully asserts said rejection is improper as there is no motivation to combine the references.

VII. GROUPING OF CLAIMS (37 C.F.R. § 1.192(c)(7))

Claims 1-25 are presently pending in this appeal. For purposes of this appeal, the pending claims are grouped in three groups. A first group comprising claims 1-13, 17 and 18. A second group comprising claims 14-16. A third group comprises claims 19-25.

VIII. ARGUMENT REGARDING THE EXAMINER'S REJECTION UNDER 35 U.S.C. § 103(a) (37 C.F.R. § 1.192(c)(8)(v))

A. The Examiner has failed to establish a *prima facie* case of obviousness under 35 U.S.C. § 103(a).

1. Claims 1-13, 17 and 18

A criteria to establish a *prima facie* case of obviousness is that there must be some suggestion or motivation either in the references themselves or in the knowledge generally available to one of ordinary skill in the art to combine the reference teachings. MPEP 2142-2143. In re Vaeck, 947 F.2d 488, 20 USPQ 2d 1438 (Fed. Cir. 1991). Applicant submits that there is no motivation to combine the Desai reference with the Gehrman reference.

First, the Gehrman reference and Desai reference disclose two distinct forms of delivery. Gehrman discloses a liquid suspension of dry viable *Lactobacillus* cells in sunflower seed oil. Desai et al. teaches a microemulsion of marine animal oils, present as microspheres or macrospheres, encased within gelatin. Due to the distinct forms of the references, i.e., a liquid versus a gel, it is not reasonable to infer that the combination of the references would in fact lead to the formulation of a stabilized and shelf-stable mixture for use in various product mixtures.

Secondly and most importantly, the Gehrman and Desai references teach away from the Examiner's suggested combination. In general, a reference may be said to teach away from its combination with a second reference if a person of ordinary skill in the art, upon reading the first reference, would be led in a direction divergent from the path that was taken by the Applicant. In *re Gurley*, 27 F.3d 551, 31 USPQ 2d 1130 (Fed. Cir. 1994). As stated previously, the Gehrman reference teaches away from utilizing the elements of Desai because the Gehrman reference states that sunflower seed oil is preferably the "**only**" liquid ingredient of the medium. See Column 2, lines 61-63 of Gehrman. Even more explicitly, the Gehrman reference states that testing the preservation properties of other oils leads to the conclusion that, "...sunflower oil has special properties for maximizing the preservation of Lactobacilli in oil suspension." See Column 5, lines 21-23. Not only would combining the fish oil and antioxidants of Desai with Gehrman nullify the desired invention of Gehrman, i.e., a suspension medium having sunflower oil as its only liquid, it would also be contrary to the teaching of Gehrman which explicitly categorizes sunflower oil, as having special, advantageous preservation properties.

In light of the Gehrman reference, it cannot reasonably be said that a person skilled in the art would infer that the addition of fish oil or antioxidants would result in the formulation of a stabilized and shelf-stable mixture in light of the special preservation properties of sunflower oil as described by Gehrman. Instead, a person of reasonable skill in the art would avoid adding the fish oil and antioxidants of Desai for fear of detrimentally effecting the special preservation properties of sunflower oil as described by Gehrman. Furthermore, it cannot reasonably be asserted that a person skilled in the art would be motivated to combine the fish oil and

antioxidants of Desai such that the sunflower oil of Gerhman, including its special preservation properties, is present at a weight percent of only 45-55%, as claimed by the present invention.

The present claims are directed to a composition with 45% to 55% vegetable oil. On the other hand, the Desai reference teaches a composition wherein the gelatin comprises anywhere from 30% to 75% by weight of the product (See Column 6, Lines 12-45) while the marine animal oil comprises at least 5%, but most preferably 25% to 75% of the product by weight (See Column 5, Line 65 – Column 6, Line 45). The preferred ranges described and the specific embodiments contemplated by the Desai reference simply do not allow for the inclusion of 45% to 55% vegetable oil. Thus, the Desai reference teaches away from Applicant's claimed invention as well as teaching away from its combination with the Gehrman reference to modify the teachings of the Gehrman reference to obtain Applicant's claimed invention.

Due to the fact that there is no suggestion or motivation to combine the cited references and that instead, the references teach away from such a combination, the modification suggested by the Examiner can only be based on hindsight using Applicant's specification as a template to guide the modification. Such hindsight reasoning based on Applicant's own specification is not appropriate. See MPEP 2141.01(III).

The Examiner rejected Applicant's arguments based on an assertion that the motivation to combine flowed from the fact that both references were directed to compositions comprising oil. But this analysis reduces a Graham analysis, as mandated by the Supreme Court, to a triviality and neglects the statutory mandate for an obviousness analysis to be based on "the whole" with respect to the claim and the cited art. See, for example, MPEP 2141.02 AND 35 U.S.C. § 103(a). As summarized by the MPEP 2141.02 in a bold heading - "**PRIOR ART**

MUST BE CONSIDERED IN ITS ENTIRITY, INCLUDING DISCLOSURES THAT TEACH AWAY FROM THE CLAIMS." Furthermore, the fact that references can be combined does not render the combination obvious unless the prior art suggests the desirability of the combination. MPEP2143.01, citing In re Mills, 16 U.S.P.Q.2d 1430, (Fed. Cir. 1990).

Applicant respectfully submits that the Examiner has failed to establish a case for *prima facie* obviousness and requests that the rejection of claims 1-13, 17 and 18 under 35 USC § 103(a) be withdrawn.

B. Claims 14-16

The Examiner has the burden to establish *prima facie* unpatentability. Furthermore, obviousness must be based on the teaching in the art of all of the claim features. See, for example, MPEP 2143.03, entitled, "All Claim Limitations Must Be Taught or Suggested." Yet, the Examiner has stated nothing regarding the features of claims 14-16. Therefore, *prima facie* obviousness has clearly not been established for these claims.

Applicant respectfully requests withdrawal of the rejection of claims 14-16.

C. Claims 19-25

A criteria to establish a *prima facie* case of obviousness is that there must be some suggestion or motivation either in the references themselves or in the knowledge generally available to one of ordinary skill in the art to combine the reference teachings. MPEP 2142-2143. In re Vaeck, 947 F.2d 488, 20 USPQ 2d 1438 (Fed. Cir. 1991). As discussed previously with respect to claims 1-13, 17 and 18, Applicant, based on the same reasoning as previously



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supplied with respect to claims 1-13, 17 and 18, again submits that there is no motivation to combine the Desai reference with the Gehrman reference.

Secondly, even if the Desai reference and the Gehrman reference are combined, the combination fails to disclose a step of heating and mixing a combination of vegetable oils and fish oils to create a clear and homogeneous mixture. "To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art." MPEP 2143.03, citing *In re Royka*, 180 U.S.P.Q. 580, (CCPA 1974). As this step is neither taught nor suggested by the Desai and Gehrman references, the Examiner has failed to establish *prima facie* obviousness.

Respectfully submitted,

Kimberly K. Baxter
Registration No. 40,504

Patterson, Thuente, Skaar & Christensen, P.A.
4800 IDS Center
80 South 8th Street
Minneapolis, Minnesota 55402-2100
Telephone: (612) 349-5750

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IX. APPENDIX (37 C.F.R. § 1.192(c)(9))

The claims involved in this appeal are provided below.

1. (Original) A palatable viscous carrier for ingestible substances subject to degradation by environmental factors such as oxidation, hydrolysis, or low pH comprising in weight percent based upon the weight of the palatable viscous carrier:

from 45% to 55% vegetable oil;

from 1% to 5% fish oil; and

from 0.25% to 1.0% exogenous antioxidants.

2. (Original) The carrier as claimed in claim 1, in which the vegetable oil comprises one or more substances selected from a group consisting of canola oil, helianthus annus oil, hydrogenated vegetable oil, borage seed oil, evening primrose oil, avocado oil, sweet almond oil, canola oil, grape seed oil, jojoba oil, apricot kernal oil, safflower oil, sesame oil, hybrid safflower oil, soybean oil, sunflower seed oil, and macadamia nut oil.

3. (Original) The carrier as claimed in claim 1, in which the fish oil comprises one or more substances selected from a group consisting of cod liver oil, tuna oil, salmon oil, and sardine oil.

4. (Original) The carrier as claimed in claim 1, in which the exogenous antioxidant comprises tocopherol.

5. (Original) The carrier as claimed in claim 4, in which the tocopherol comprises one or more substances selected from a group consisting of alpha tocopherol, beta tocopherol, gamma tocopherols and delta tocopherols.

6. (Original) The carrier as claimed in claim 1, further comprising one or more substances selected from a group consisting of flavoring, plant extracts, starches, hydrophobic polyols, and coloring agents.

7. (Original) A palatable probiotic ingestible food supplement in a viscous carrier, the food supplement comprising in weight percent based upon the weight of the palatable probiotic ingestible food supplement:

from 45% to 55% vegetable oil;

from 1% to 5% fish oil; and

from 0.25% to 1.0% exogenous antioxidants; and

from 0.1% to 5% probiotic ingredients.

8. (Original) The food supplement as claimed in claim 7, in which the vegetable oil comprises one or more substances selected from a group consisting of canola oil, helianthus annus oil, hydrogenated vegetable oil, borage seed oil, evening primrose oil, avocado oil, sweet almond oil, canola oil, grape seed oil, jojoba oil, apricot kernal oil, safflower oil, sesame oil, hybrid safflower oil, soybean oil, sunflower seed oil, and macadamia nut oil.

9. (Original) The food supplement as claimed in claim 7, in which the fish oil comprises one or more substances selected from a group consisting of cod liver oil, tuna oil, salmon oil, and sardine oil.
10. (Original) The food supplement as claimed in claim 7, in which the exogenous antioxidant comprises tocopherol.
11. (Original) The food supplement as claimed in claim 10, in which the tocopherol comprises one or more substances selected from a group consisting of alpha tocopherol, beta tocopherol, gamma tocopherols, and delta tocopherols.
12. (Original) The food supplement as claimed in claim 7, further comprising one or more substances selected from a group consisting of flavoring, plant extracts, starches, hydrophobic polyols, and coloring agents.
13. (Original) The food supplement as claimed in claim 7, in which the probiotic ingredients comprise one or more substances selected from a group consisting of freeze-dried probiotic microorganisms, antibiotics, oil soluble, and water soluble vitamins, enzymes, salts of bioactive ingredients and polysaccharides.
14. (Original) The food supplement as claimed in claim 7, further comprising papain.

15. (Original) The food supplement as claimed in claim 17, in which the probiotic ingredients is one or more substances selected from a group consisting glucosamine hydrochloride, glucosamine sulfate, and chondroitin sulfate.

16. (Original) The food supplement as claimed in claim 7, further comprising fructooligosaccharides.

17. (Original) The food supplement as claimed in claim 7, in which the probiotic ingredients comprise microorganisms.

18. (Original) The food supplement as claimed in claim 17, in which the microorganisms comprise one or more selected from a group consisting of lactobacillus acidophilus, lactobacillus rhamnosus, enterococcus faecium, lactobacillus helveticus, and lactobacillus plantarum
lactobacillus acidophilus, lactobacillus rhamnosus, and lactobacillus plantarum.

19. (Original) A method for delivering probiotic substances utilized in dietary supplements to an intestinal tract, the method comprising the steps of:

heating and mixing natural occurring ingestible oils comprising vegetable oils and fish oils until a resulting mixture is clear and homogeneous;

cooling said resulting mixture to a viscous state and to a temperature that will not harm the probiotic substances;

adding the probiotic substances to the cooled mixture and mixing such that the probiotic substances are coated with the cooled mixture whereby an ingestible, viscous dietary supplement is produced.

20. (Original) The method as claimed in claim 19, in which the vegetable oils are selected from a group consisting of canola oil, helianthus annus oil, hydrogenated vegetable oil, borage seed oil, evening primrose oil, avocado oil, sweet almond oil, canola oil, grape seed oil, jojoba oil, apricot kernal oil, safflower oil, sesame oil, hybrid safflower oil, soybean oil, sunflower seed oil, and macadamia nut oil.

21. (Original) The method as claimed in claim 19, in which the fish oils comprise one or more substances selected from a group consisting of cod liver oil, tuna oil, salmon oil, and sardine oil.

22. (Original) The method as claimed in claim 19, further comprising the step of adding one or more substances selected from a group consisting of flavoring, plant extracts, starches, hydrophobic polyols, and coloring agents.

23. (Original) The method as claimed in claim 19, in which the probiotic substances comprise one or more substances selected from a group consisting of freeze-dried probiotic microorganisms, antibiotics, oil soluble, and water soluble vitamins, enzymes, salts of bioactive ingredients, and polysacharides.

24. (Original) The method as claimed in claim 19, in which the probiotic substances comprise one or more substances selected from a group consisting glucosamine hydrochloride, glucosamine sulfate, and chondroitin sulfate.

25. (Original) The method as claimed in claim 19, in which the probiotic substances comprise one or more microorganisms selected from a group consisting of lactobacillus acidophilus, lactobacillus rhamnosus, enterococcus faecium, lactobacillus helveticus, and lactobacillus plantarum lactobacillus acidophilus, lactobacillus rhamnosus, and lactobacillus plantarum.